

## AMENDMENT

### **In the Claims:**

Prior to further action on the merits, please cancel claims 5-14, without prejudice or disclaimer, as being drawn to non-elected subject matter pursuant to a restriction requirement. Please amend claims 15 and 16 as follows:

15. (Twice Amended) Composition for plant protection in agriculture and forestry and/or in horticulture comprising at least one compound according to any one of claims 1, 2, 3 or 4, optionally in addition to at least one carrier and/or diluent.

16. (Twice Amended) Therapeutic composition comprising at least one compound according to any one of claims 1, 2, 3 or 4, optionally in addition to at least one carrier and/or diluent.

## REMARKS

### **I. Status of Claims**

Claims 1-4, 15 and 16 are pending in the instant case and stand variously rejected under 35 U.S.C. §102(e), 35 U.S.C. §112, second paragraph and obviousness-type double patenting. Applicants traverse the rejections.

Claims 5-14 have been canceled herein by amendment as drawn to non-elected subject matter. This amendment to restrict the pending claims to the elected invention is made solely to comply with Patent Office restriction requirement practice and not in response to any rejection or in order to comply with any patentability requirement. The amendment is made without prejudice and Applicants reserve the right to prosecute these claims in continuing applications at a later date.

Applicants have amended claims 15 and 16. Attached hereto is a marked-up version of the changes made to the claims entitled "Version of Markings to Show Changes Made" (Appendix A). The amendments made herein are fully supported by the specification as filed and Applicants' representative verifies that the amendments do not add new matter to the specification. Claims 15 and 16 have been amended to be multiply dependent from claims 1, 2, 3 or 4; this amendment is supported by claims 15 and 16 as originally filed. In

the preliminary amendment filed May 17, 1999, Applicants amended claims 15 and 16 to conform to U.S. practice, however in doing so, Applicants inadvertently neglected to ensure that the compositions of claims 15 and 16 encompassed compositions comprising Epothilone D, which was originally contemplated by claims 15 and 16 as filed. The present amendment rectifies this oversight.

Applicants believe the response and amendments presented herein overcome the rejections placing the instant case in condition for allowance. An early indication of such favorable action is respectfully solicited from the Examiner.

**II. Claims 3 and 4 Were Improperly Withdrawn by the Examiner and Should Be Rejoined with the Claims Presently under Consideration.**

The present application contained claims 1-16 as originally filed. On September 27, 2000 the Examiner issued a 6-way restriction requirement in which Group I was indicated as claims 1-4 drawn to Epothilones C and D. In response to the restriction requirement on October 27, 2000, Applicants provisionally elected the claims of Group I *with traverse* requesting rejoinder of Group V (claim 15), directed to a composition comprising at least one compound according to claim 1, optionally in addition to at least one carrier and/or diluent and Group VI (claim 16) drawn to a therapeutic composition comprising at least one compound according to claim 1, optionally in addition to at least one carrier and/or diluent to the claims of Group I.

In the instant official action, the Examiner states that "claims 3-14 are withdrawn ...as being drawn to non-elected inventions. Election was made **without** traverse in paper No. 8" (emphasis as in original). Applicants respectfully traverse. As indicated above, in response to the initial restriction requirement, Applicants elected the claims of Group I *with traverse*. Moreover, the claims of Group I are claims 1, 2, 3 and 4 and not, as the Examiner seems to be suggesting, only claims 1-2.

The instant Office Action examined claims 1, 2 as well as 15 and 16 thereby indicating that Applicants reasons for traversal of the initial restriction requirement were considered and the claims of Groups V and VI were rejoined with those of Group I. Applicants request that the Examiner affirmatively make such a rejoinder of record.

In light of the above comments, Applicants submit that it is clear that the claims under consideration are claims 1-4, 15 and 16.

### **III. Rejections under 35 U.S.C. 102 should be withdrawn.**

The Examiner rejected Claims 1, 2 and 15 and 16 under 35 U.S.C. 102(e) as allegedly being anticipated by the either U.S. Patent No. 5,969,145 or U.S. Patent No. 6,043,372. Applicants respectfully traverse the rejection.

U.S. Patent No. 6,043,372 is a divisional of U.S. Patent No. 5,969,145 and as such the specifications of the two patents are substantially identical. U.S. Patent 5,969,145 was filed on September 2, 1997 and depends from U.S. Provisional Application Number 60/027,480 filed September 26, 1996. According to the Examiner, the disclosure of the U.S. Patent No. 5,969,145 (or U.S. Patent No. 6,043,372) anticipates the claims 1, 2, 15 and 16 of the instant invention directed to Epothilone C.

Anticipation of a claim requires that the reference teach every element of the claim. M.P.E.P. §2131. Thus, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreover, in order to carry back the 35 U.S.C. §102(e) critical date of a U.S. Patent reference to the filing date of a parent application, the parent application must support the invention claimed as required by 35 U.S.C. §112, first paragraph. “For if a patent could not theoretically have issued the day the application was filed, it is not entitled to be used against another as ‘secret art’” under 35 U.S.C. §102(e). *In re Wertheim* 646 F2d 527, 537, 209 USPQ 554, 564 (CCPA, 1981).

Attached herewith as Appendix B is a certified copy of U.S. Provisional Application Number 60/027,480 which is the provisional application that serves as the parent of the U.S. Patent 5,969,145. The only disclosure of Epothilone C in U.S. Patent 5,969,145 relied on by the Examiner in order to anticipate the claims of the instant invention is found at column 24 lines 1-20 wherein the structures of Epothilone C and D are described, (the corresponding disclosure in U.S. Patent No. 6,043,372 is found at column 23 lines 32-52). Applicants have reviewed the disclosure of U.S. Provisional Application Number 60/027,480 and have found no teaching or suggestions that corresponds to this disclosure in the U.S.

Patent 5,969,145. As such, the filing date of U.S. Provisional Application Number 60/027,480 cannot be used as the critical date for disclosure of Epothilone C and D in U.S. Patent 5,969,145 because U.S. Provisional Application Number 60/027,480 could not theoretically have issued with claims directed to Epothilone C or Epothilone D. As such, the effective 35 U.S.C. §102(e) critical date of U.S. Patent 5,969,145 is **September 2, 1997**.

Claim 1 of the present invention is directed to Epothilone C. Claim 4 of the instant invention is directed to Epothilone D. The instant application claims priority of Federal Rep. Germany application 196 47 580.5 which was filed November 18, 1996 and Federal Rep. Germany application 197 08 506.1 which was filed 26 February 1997. Attached herewith as Appendix C and Appendix D respectively, are certified copies of these documents. Application 196 47 580.5 describes preparation and compositions of Epothilones C and D. Thus, the claims of the instant invention, directed to Epothilones C and D, are entitled to a priority date of **November 18, 1996**. Thus, Applicants submit that the 35 U.S.C. §102(e) date of U.S. Patent 5,969,145 of September 2, 1997 is antedated by Applicants' earlier filed foreign priority application 196 47 580.5 which described the preparation and compositions of Epothilones C and D in a manner sufficient to support the requirements of 35 U.S.C. §112, first paragraph. As such, Schinzer is not prior art against Claim 1.

Claim 2 describes a specific Epothilone having a structural formula  $C_{26}H_{39}NO_5S$  characterized by specific NMR data indicated in Table 1 of the specification. Neither the formula nor the characteristic data are disclosed by any of the Schinzer documents because none of the Schinzer documents provide a teaching or even suggestion of Epothilone C prior to the priority date of the claims of the instant application. Applicants submit that in the absence of such a disclosure the Schinzer documents cannot anticipate claim 2.

Claims 15 and 16 each ultimately depend from claims 1, 2, 3 or 4. Therefore, Applicants assert that these claims also are not anticipated by either of the Schinzer documents. While the Examiner's rejection was directed at claims 1, 2, 15 and 16, for completeness Applicants believe that the above discussion also addresses any similar rejections that the Examiner may set forth against claims 3 and 4. Specifically, as indicated above claim 3 is directed to Epothilone D. The only reference to Epothilone D in U.S. Patent 5,969,145 is found at column 24 lines 1-20. Applicants foreign priority application 196 47

580.5 fully described the preparation and compositions of Epothilone D before the critical 35 U.S.C. §102(e) date of Schinzer. As such, Schinzer is not prior art against Claim 3.

Claim 4 describes a specific Epothilone having a structural formula  $C_{27}H_{41}NO_5S$  characterized by specific NMR data indicated in Table 1 of the specification. Neither the formula nor the characteristic data are disclosed by any of the Schinzer documents because none of the Schinzer documents provide a teaching or even suggestion of Epothilone D prior to the priority date of the claims of the instant application. Applicants submit that in the absence of such a disclosure the Schinzer documents cannot anticipate claim 4.

In light of the above discussions, Applicants submit that neither U.S. Patent No. 5,969,145 nor U.S. Patent No. 6,043,372 are prior art to the claims of the instant invention. As such, Applicants request that the rejection be withdrawn and the claims be reconsidered for allowance.

**IV. Rejection of the Claims under 35 U.S.C. §112, second paragraph should be withdrawn**

The Examiner rejected claim 2 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. More particularly, the Examiner stated that the recitation of properties does not differentiate over the structure recited in claim 1. Applicants traverse.

Claim 2 describes a specific Epothilone having a structural formula  $C_{26}H_{39}NO_5S$  characterized by specific NMR data indicated in Table 1 of the specification. The MPEP at 2173 clearly sets forth purposes of the definiteness requirement. Claim 2 as presented in the present application is sufficiently definite to comply with these purposes. Firstly, Applicants submit that the claim language of claim 2 is such that it ensures the scope of the claim is clear so the public is informed of the boundaries of the claim: it provides a specific formula and data that correlate with that formula. Moreover, Applicants submit that the terms of the claim are imbued with sufficient clarity so that it can be determined whether the claimed invention meets the criteria for patentability. In light of these comments Applicants submit that claim 2 is definite. To the extent that the Examiner may advance similar objections to claim 4, Applicants submit that the same observations are applicable to

any such objection to claim 4 because that claim too recites another specific formula ( $C_{27}H_{41}$   $NO_5S$ ) and data that correlate with that formula.

Applicants submit that claims 2 and 4 are definite and are in full compliance with 35 U.S.C. §112, second paragraph and therefore request that the rejection be withdrawn and the claims be allowed to proceed to allowance.

#### **V. The Double Patenting Rejection is Improper and Should be Withdrawn**

The Examiner rejected claims 1 and 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent 5,969,145. Applicants traverse this rejection.

The judicially created doctrine of obviousness-type double patenting rejection applies to the claims of an Applicant's application to the claims of *an Applicant's* patent (or two claims in the same application, or claims in a first application of the Applicant to claims in another application of the Applicant) (see MPEP §804). An obviousness-type rejection does not apply to a comparison of an Applicant's claims with those of a patent issued to *another*. As such, the obviousness-type double patenting rejection set forth by the Examiner is legally improper. Applicants respectfully request that the rejection be withdrawn.

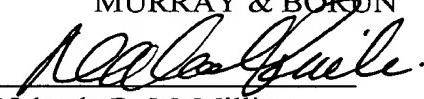
#### **VI. Conclusion.**

Applicants believe all the claims are now in a condition for allowance. Favorable reconsideration of the application is respectfully requested. The Examiner is invited to contact the undersigned with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,  
MARSHALL, O'TOOLE, GERSTEIN,  
MURRAY & BORJN

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By:

  
Nabeela R. McMillian  
Registration No. 43,363  
Agent for Applicants  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, Illinois 60606-6402  
(312) 474-6300